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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT NO. 3: INVALIDITY OF U.S. PATENT NO. 5,714,504 - CLAIMS 1-2, 4, 6 AND 7 BASED ON "SOLID STATE"

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Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively "Hanmi") respectfully submit this Memorandum in Support of their Motion for Summary Judgment No. 3: Invalidity of Claims 1, 2, 4, 6 and 7 of U.S. Patent No. 5,714,504 ("the '504 patent" (D.I. 86-2))[1] in this Hatch-Waxman patent infringement action brought by Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca" or "plaintiffs").

I. INTRODUCTION AND BRIEF SUMMARY

This motion focuses on claim language presented for the first time during prosecution – characterizing the alkaline salt in each of independent claims 1, 6 and 7 at issue as "solid state" as part of AstraZeneca's successful effort to overcome prior art. Critically, the term "solid state" appears nowhere in the original '504 patent application. This term has no recognized meaning in describing pharmaceutical substances. Its inclusion in the '504 claims is a clear violation of the written description requirement. Because the '504 patent does not describe how to make a such a "solid state" substance, the claims are not enabled. And, since no one can tell if a proposed product is "solid state" in the context of the '504 patent, the claims are fatally indefinite.

Hanmi has submitted New Drug Application ("NDA") No. 202342 filed under Section 505(b)(2) (21 U.S.C. § 355(b)(2)) seeking approval to market esomeprazole *strontium* capsules in the United States. Hanmi's NDA is directed to an original strontium salt formulation of esomeprazole (SOF ¶¶ 1-2[2]), for which Hanmi has been issued its own patent (Ex. 6[3]).

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[1] This motion addresses the asserted claims of the '504 patent – claims 1, 2, 4 and 6-7. The remaining claims 3, 5 and 8-10 are the subject of Hanmi's Motion No. 5, which seeks a judgment of non-infringement. As indicated in Hanmi's Motion for Summary Judgment No. 5, AstraZeneca has moved to belatedly assert infringement of claims 3, 5 and 10. If AstraZeneca's motion is granted, the grounds in support of the present motion would also invalidate claims 3, 5 and 10 and Hanmi hereby contingently seeks such a judgment.

[2] "SOF" refers to the contemporaneously filed Local Rule 56.1 Statement of Undisputed Material Facts in Support of Defendants' Motions for Summary Judgment Nos. 3, 4 and 5 regarding

AstraZeneca is the holder of approved NDA No. 21-553, which permits the marketing and sale of its product, Nexium® (esomeprazole magnesium trihydrate). SOF ¶ 3.

Hanmi sent to AstraZeneca a Notice of a Paragraph IV Certification, against each of AstraZeneca's eleven listed Orange Book patents for Nexium®, including the '504 patent and U.S. Patent No. 5,877,192 on which AstraZeneca brought the instant action. SOF ¶ 4.

On May 18, 2011, pursuant to the Court's schedule for this case, AstraZeneca alleged infringement of claims 1, 2, 4, 6 and 7 of the '504 patent based on the product identified in Hanmi's NDA 202342. SOF ¶ 5. Months after receiving Hanmi's Non-infringement and Invalidity Contentions, AstraZeneca belatedly moved to additionally assert claims 3, 5 and 10 in this action. (D.I. 81-82.) Hanmi has opposed. (D.I. 86.) AstraZeneca has not asserted claims 8 or 9.[4] SOF ¶ 6. Regardless of the outcome of AstraZeneca's motion, it cannot be disputed that the '504 patent does not describe or enable any "solid state" alkaline salt of (-)-omeprazole.

The instant motion seeks summary judgment that, based on the undisputed record before the Court, claims 1, 2, 4, 6 and 7 of the '504 patent are invalid based on the failure to comply with the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, as well as the "definiteness" requirement of 35 U.S.C. § 112, second paragraph, because the term "solid state" is not described or enabled, and is indefinite.

The asserted claims of the '504 patent are directed to formulations and methods comprising "solid state" alkaline salts of (-)-omeprazole. Yet nowhere in the '504 patent specification (or the original patent application resulting in the issuance of the '504 patent) is the

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invalidity of the asserted claims (Motion Nos. 3 and 4) and non-infringement of the unasserted claims (Motion No. 5) with respect to United States Patent No. 5,714,504.

[3] All exhibits referenced herein are cited in the Declaration of Renita S. Rathinam submitted herewith.

[4] See Hanmi's concurrently filed Motion for Summary Judgment No. 5: Non-Infringement of Unasserted Claims.

term "solid state" alkaline salt mentioned, much less defined or described. SOF ¶¶ 13-14, 26, 29-31. The term is not contained in the original claims of the original application as filed. SOF ¶¶ 26-28. The examples provide no guidance, and it is entirely unclear whether the products described are "solid state" alkaline salts of (-)-omeprazole. Several examples disclose "solid" products that are formed, but this Court has already rejected the definition of "solid state" as simply meaning "solid" or "solid form." *AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd, et al.*, Civ. No. 05-5553 (JAP) (consolidated case), 2010 U.S. Dist. LEXIS 48844 (D.N.J. May 17, 2010) ("*AZ v. DRL*") (SOF ¶¶ 65, 66). As established herein, there is no uniform art-recognized meaning of "solid state" for use as a descriptor of each and every given pharmaceutical substance.

Moreover, for the reasons set forth below, and as argued by AstraZeneca during prosecution, the field of alkaline salts of (-)-omeprazole was nascent in the 1990's and therefore the technology demanded increased disclosure in order to show "possession" of the claimed subject matter – which was never provided. *Carnegie Mellon Univ. v. Hoffmann La Roche Inc.*, 541 F.3d. 1115, 1126 (Fed. Cir. 2008); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (*en banc*).

Nor does the patent specification disclose how to make "solid state" alkaline salts of (-)-omeprazole, because AstraZeneca failed to explain that term in the context of the '504 patent. Thus, a person of ordinary skill in the art could not determine how to make "solid state" alkaline salts of (-)-omeprazole.

Finally, the asserted claims are fatally indefinite under 35 U.S.C. § 112, second paragraph, because the term "solid state" alkaline salts fails to notify "the public of the [scope of the] patentee's right to exclude," *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1338 (Fed.

Cir. 2003), preventing a "potential competitor to determine whether or not he is infringing." *See Morton Intl, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

The claim term "solid state" has already been considered by the Court in *AZ v. DRL* as having plain meaning (SOF ¶¶ 65-66), and neither party seeks a construction here. Thus, resolution of this motion simply requires consideration of the term to the undisputed facts filed herewith in light of controlling precedent.

II. ARGUMENT

A. The Standard For Summary Judgment

"[S]ummary judgment is as appropriate in a patent case as in any other," when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *Avia Group Int'l, Inc. v. L.A. Gear Calif., Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). It is well settled that "the statutory purposes of the grant of summary judgment under Fed. R. Civ. P. 56 are without question intended to be effectuated in patent litigation as in any other type of suit and in accordance with the same standard." *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 1571 (Fed. Cir. 1984). "[C]ourts should not hesitate to avoid an unnecessary trial by proceeding under Fed. R. Civ. P. 56 without regard to the particular type of suit involved." *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 779 (Fed. Cir. 1983).

A party seeking summary judgment may meet its initial responsibility by showing that there is no genuine issue of fact as to an essential element of the infringement case. *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043 (Fed. Cir. 2001). When the moving party has done so, the burden shifts to the non-moving party to establish the existence of an issue of fact that could affect the outcome of the litigation and from which a reasonable jury could find for the opponent. *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1476 n.20 (9th Cir. 1996). Where a party fails to make a showing sufficient to establish an element essential to that party's

case, and on which that party bears the burden of proof at trial, summary judgment must be entered against that party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. Claims 1-2, 4 And 6-7 Are Invalid Under 35 U.S.C. § 112, First Paragraph, For Lack Of Written Description

Under 35 U.S.C. § 112, first paragraph, the patent specification must contain a written description of both the invention and of the manner and process of making and using the invention. 35 U.S.C. § 112; *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (*en banc*). The essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed. *Id.* at 1350. The test for sufficiency of the description is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had *possession* of the claimed subject matter as of the filing date. *Id. See also Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). Since the hallmark of written description is disclosure, "possession as shown in the disclosure" is a formulation for evaluating written description. *Ariad*, 598 F.3d at 1351; *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (Adequate written description means that the applicant, in the specification, must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the [claimed] invention.") (emphasis added). For the reasons set forth below, the '504 patent does not convey to a person of ordinary skill that the inventors were in possession of non-described "solid state" alkaline salts at the time of filing, and the asserted claims therefore are invalid under 35 U.S.C. § 112, first paragraph.

1. The "Solid State" Salts Of The Asserted Claims Are Not Described In The '512 Application

Claims 1-2, 4 and 6-7 of the '504 patent all recite a "solid state" alkaline salt. Yet the term "solid state" appears nowhere in the '504 patent specification (including the examples) which issued from U.S. Patent Application No. 08/376,512 ("the '512 application") (SOF ¶ 13, 14, 26), and nowhere is the term defined or otherwise described as required under Section 112. The term "solid state" was never present in the original '512 application or its claims as filed on January 23, 1995 as descriptors of the originally disclosed salt compounds – not in the specification, the claims or the abstract. SOF ¶¶ 26-31; Declaration of Wayne J. Genck, Ph.D ("Genck Decl.") ¶ 36. On its face, the "solid state" alkaline salt requirement of all of the '504 patent claims is new matter,[5] not present in the '512 application when filed, or in the specification of the '504 patent as issued. *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009) ("The written description doctrine prohibits new matter from entering into claim amendments, particularly during the continuation process."). Because "solid state" has not been described or defined anywhere in the '504 patent or original '512 application as filed, the asserted claims are invalid under 35 U.S.C. § 112, first paragraph. *Centocor Ortho Biotech v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011) ("A patent also can be held invalid for failure to meet the written description requirement based solely on the face of the patent

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[5] The Manual of Patent Examination and Procedure (MPEP) defines "new matter" as:

> Matter not in the original specification, claims or drawings is usually new matter. Depending on the circumstances such as the adequacy of the original disclosure, the addition of inherent characteristics such as chemical or physical properties, a new structural formula or a new use may be a new matter.

MPEP § 608.04(a) (Ex. 29) (citing *Ex parte Vander Wal,* 109 U.S.P.Q. (BNA) 110 (Bd. App. 1955)).

specification.") (citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004)).

The prosecution history confirms that the inventors were not in *possession* of the claimed "solid state" alkaline salts as of the filing date of the '512 application. As filed, the '512 application contained 34 claims. None of the claims as filed mentioned a "solid state" alkaline salt. SOF ¶¶ 27-31; Genck Decl. ¶ 38. No aspect of the original '512 specification described, discussed or referred to a "solid state" alkaline salt of the (-)-enantiomer of omeprazole. SOF ¶¶ 29-31; Genck Decl. ¶ 38. The claimed recitation of "solid state" alkaline salts originated after filing of the '512 application, during prosecution. SOF ¶ 37; Genck Decl. ¶ 41.

Following the August 12, 1996 rejection of claims as anticipated and as obvious (SOF ¶¶ 32, 33), the term "solid state" appears for the first time in the prosecution history in a January 21, 1997 Examiner interview summary record. According to the summary record, and based on an interview with the Applicant, the Examiner stated "a pharmaceutical formulation for oral administration of pure *solid state* enantiomers of omeprazole Na-salt may be allowable after reviewing the data in affidavit form. This is because the prior art teach[es] that (+), (-), (+,-), show same activity in vitro. [ ] and in vivo." (Ex. 3) (citations omitted) (emphasis added). The Examiner concluded that "the scope of the claim will depend on the data submitted." SOF ¶ 36; Genck Decl. ¶ 40.

Applicants responded February 12, 1997 by canceling all then-pending claims (1-34) and adding new claims 35-44 (now issued as claims 1-10 of the '504 patent) directed to "solid state" alkaline salts. SOF ¶ 37. Applicants argued that "[t]he new claims reflect the *patentable distinctions* discussed during the interview and are drawn to a pharmaceutical formulation comprising a pure *solid state* alkaline salt of the (-)-enantiomer of omeprazole and a pharmaceutical carrier." SOF ¶ 38 (emphasis added).

Critically, AstraZeneca did not point out *where* in the original specification there existed support for a "solid state" alkaline salt. *Id.* The Federal Circuit has made clear, however, that the addition of new matter to the claims requires consideration of whether the new matter has been described in the original disclosure:

> When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a *different invention* than was the original claim, it is proper to inquire whether the newly claimed subject matter was *described* in the patent application when filed as the invention of the applicant. That is the essence of the so-called "description requirement" of § 112, first paragraph.

In re Wright, 866 F.2d 422, 424 (Fed. Cir. 1989) (emphasis in original).

Without a doubt, the addition of "solid state" to the claims by way of amendment constituted new matter, in violation of Section 132 of the Patent Act, which provides that "no amendment shall introduce new matter into the disclosure of the invention." 35 U.S.C. § 132; *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office."). AstraZeneca's only possible argument in response would be that the "solid state" limitations added by amendment were *inherently* contained in the original application. *See Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1438 (Fed. Cir. 1984). Here, they could not have been because, as shown below, there was no single art-recognized meaning of that term in the context of the '504 patent.

In their remarks filed with the Amendment, AstraZeneca distinguished the Kohl reference – which disclosed (-)-omeprazole and exemplified (+)-omeprazole, obtained as an amorphous solid and salts thereof – by stating that the reference did not disclose *the pure solid state salt form* of the (-)-enantiomer of omeprazole. SOF ¶¶ 32-34, 39; Genck Decl. ¶ 39, 42.

AstraZeneca argued that "[t]he pure solid state salt form of the (-)-enantiomer of omeprazole of this invention provides advantages of purity, long term chemical stability, and chiral stability," and that "[n]one of these properties or advantages are disclosed in the cited prior art." SOF ¶ 39. AstraZeneca added that "[t]he unexpected pharmacokinetic properties of the (-)-enantiomers of omeprazole *coupled with the ability to prepare the (-)-enantiomer in a pure solid state form* allow for the present invention of a more efficacious pharmaceutical formulation." *Id.* (emphasis added).

By distinguishing the "solid state" salt form of the (-)-enantiomer of omeprazole in the then-pending claims from the amorphous solid form of the (+)-enantiomer of Example 6 of the Kohl reference, and salts thereof, AstraZeneca made clear that the claimed "solid state" forms were different from the "amorphous solid" forms and salts thereof of the prior art. Genck Decl. ¶ 44.[6] Thus, the intrinsic records supports the Court's prior determination that "solid state" in the '504 patent claims does not simply mean a "solid form" of the compound. *See* SOF ¶¶ 65-66. In this regard, this Court rejected AstraZeneca's proposed interpretation of "solid state" as meaning "a solid form rather than liquid, such as, a syrup or oil," because AstraZeneca provided no justification for it. *Astrazeneca AB v. Dr. Reddy's Labs., Ltd, et al.*, Civ. No. 05-5553 (JAP), 2010 U.S. Dist. LEXIS 48844 at *26 (May 18, 2010) (SOF ¶¶ 65-66). Thus, any examples or other description of the production of a solid form rather than liquid, such as a syrup or oil,

[6] The Andersson Declaration submitted during prosecution states that the '512 application describes the preparation of "the alkaline salts of each of the single enantiomeric forms of omeprazole [ ] *in solid state form which made it possible to further purify the salts by recrystallization* attaining both high chemical and optical purity." Ex. 3, February 12, 1997 Andersson Declaration at HAN0039776 (emphasis added). Therefore, if "solid state" forms according to the Declaration were those that could be further purified by recrystallization, the term would exclude the products of *e.g.*, Examples 6, 7, which are not further purified by recrystallization. *Ariad*, 598 F.3d at 1351. This statement by Dr. Andersson only confuses the intrinsic record and adds to the indefinite nature of the term.

cannot demonstrate inventors' possession of "solid state" alkaline salts at the time of filing the '512 application.

Compounding the lack of disclosure of "solid state" within the four corners of the '512 application as filed is the fact that the term "solid state" had no single plain and ordinary meaning to one skilled in the art in the 1993-1995 time frame (or even today), in the context of describing pharmaceutical substances. This is confirmed by the relevant literature. Genck Decl. ¶¶ 32-33, 45-48. Thus, any assertion by AstraZeneca that the concept of a "solid state" salt is *inherently* described in the original '512 application should be rejected. While solids are generally distinguished from liquids and gasses as different phases of matter, in the pharmaceutical development domain, the term "solid state" is not precisely defined and authors have used the term to refer to solid forms existing in a single or crystalline phase, and even to the properties associated with that phase. Other literature discusses solid state *properties* of polymorphs, hydrates, amorphous forms and desolvated solvates as including, *e.g.*, chemical and physical stability, solubility, morphology, calorimetric behavior, hygroscopicity, glass transition temperature, etc. Genck Decl. ¶¶ 45-47. Thus, whether "solid state" means some type of phase, or some type of property, is unclear.

The '512 application as filed in 1995 contains no discussion whatsoever of any of the above concepts in the reported literature. Thus, it is clear that the '512 application as filed does not expressly or inherently describe the later added claims relating to "solid state" alkaline salts of (-)-omeprazole. Based on the disclosure of the '504 patent/'512 application, one skilled in the art would not be able to tell if any contemplated alkaline salt of (-)-omeprazole would be "solid state" or not. There simply is no definition or guidance in the '504 patent, and the relevant literature reports various concepts. Genck Decl. ¶¶ 48-52.

For the foregoing reasons, the "solid state" alkaline salts of the claims, added as new matter to the claims during prosecution, are neither defined, described, nor supported in the '504 patent and thus impermissibly expand the patent disclosure beyond the scope of the original application. As a result, the asserted claims are invalid under 35 U.S.C. § 112, first paragraph.

2. AstraZeneca's Contentions Confirm That The '504 Patent Fails To Satisfy The Written Description Requirement

In an effort to salvage the failure of the '504 patent to describe "solid state" alkaline salts, AstraZeneca stated in its Responses to Hanmi's invalidity contentions that the '504 patent adequately describes "solid state" alkaline salts of (-)-omeprazole based on the patent's disclosures that:

- "the salts can be obtained as crystalline products"
- the "'alkaline salts' of the invention were distinguished over prior art disclosures of 'single enantiomers of omeprazole' that were obtained as 'syrups.'"
- Examples 1-7 of the '504 patent "afford solid state alkaline salts of (-)-omeprazole, as reflected in the generation of 'crystals' (Exs. 1, 2), 'amorphous powder' (Ex. 3), 'white powder' (Exs. 4, 5), and 'crystalline' product (Exs. 6, 7)."

SOF ¶ 67; Ex. 13 (AstraZeneca's Responses to Hanmi's Invalidity Contentions, pp. 54-55). But these arguments merely rehash AstraZeneca's earlier, rejected arguments in the DRL litigation that "solid state" means "solid as opposed to liquids such as syrups or oils" or "solid forms" – arguments this Court has already dismissed as lacking justification. SOF ¶¶ 65-66. And, they ignore the arguments AstraZeneca made during prosecution distinguishing the "solid state" materials from the amorphous solid of the prior art. *See* Section II-B-1, *supra*. By repurposing its previously unsuccessful arguments in its present contentions, AstraZeneca effectively concedes that the term "solid state" has no independent description or meaning in the context of the '504 patent.

In addition, AstraZeneca seeks to prop up the description of the "solid state" alkaline salts of the '504 patent claims by illusory reference to the publication of other salt species of (-)-

omeprazole: "[t]he inherent solid state nature of numerous other 'alkaline salts' of (-)-omeprazole of the '504 patent inventions has been confirmed, including alkaline lithium, potassium, calcium, barium, zinc and copper salts, as well as Hanmi's strontium salt." SOF ¶ 68. Yet all of the salts referred to by AstraZeneca were described in patents or published patent applications filed and published *after* the '504 patent was filed. It is well-established that a patent must satisfy the written description requirement as of the date of the filing of the application; later description cannot be added to support an earlier disclosure. *Ariad*, 598 F.3d at 1351; *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). And, again, AstraZeneca appears to equate "solid state" with "solid" in its contentions – at odds with the Court's ruling. AstraZeneca's reliance on the post-filing publications of (-)-omeprazole salts (not named in the '504 patent) as providing written description support for the subject matter as claimed is legally unrecognized and should be disregarded.

C. Claims 1-2, 4 And 6-7 Are Invalid Under 35 U.S.C. § 112, First Paragraph, For Failure To Satisfy The Enablement Requirement As A Matter Of Law

In order to satisfy the enablement requirement of Section 112, an applicant must describe the manner of making and using the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same ...." 35 U.S.C. § 112, para. 1. Enablement is determined as of the effective filing date of the patent's application – *i.e.*, January 23, 1995 for the '504 patent. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

Courts have freely granted summary judgment motions for invalidity based on lack of enablement when it is manifest that the specification does not support the full scope of the claim. *See, e.g., Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1354 (Fed. Cir. 2007) (affirming summary judgment of invalidity for nonenablement); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282-85 (Fed. Cir. 2007); *Liebel-Flarsheim Co., v. Medrad, Inc.*, 481 F.3d

1371, 1378-80 (Fed. Cir 2007) (affirming grant of summary judgment of invalidity based on nonenablement where claims covered injectors both with and without pressure jackets, and patent specification contained no disclosure of an injector without a pressure jacket); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1243-44 (Fed. Cir. 2003) (affirming grant of summary judgment of invalidity based on nonenablement where claims covered steel strips containing either a Type 1 or a Type 2 aluminum coating, and patent specification contained no disclosure of how to make and use a steel strip containing a Type 1 aluminum coating); *Sitrick v. Dreamworks, LLC, et al*, 516 F.3d 993, 1000-02 (Fed. Cir. 2008) (affirming grant of summary judgment of invalidity based on nonenablement where claims covered video and audiovisual presentations including both movies and video games and patent specification contained no disclosure as how to use the claimed systems for movies); *Pharm. Resources, Inc. v. Par Pharms., Inc.*, 253 Fed. Appx. 26, 30-31 (Fed. Cir. 2007) (unpublished) (affirming grant of summary judgment of invalidity based on nonenablement where claims covered any surfactant in any concentration and patent specification contained only three working examples including 1 new surfactant).

The law is clear that claims reciting allegedly key novel features compared to the prior art, and claims directed to nascent technologies require fully supporting disclosure in the patent specification itself.

The claims of the '504 patent do not comply with the enablement requirement of Section 112 and are therefore invalid because there is no teaching in the patent of how to make "solid state" alkaline salts of (-)-omeprazole as of the filing date of the '512 application, and a person of ordinary skill could not have done so without undue experimentation.

1. The '504 Patent Specification Fails To Teach How To Make A "Solid State" Alkaline Salt Form Of (-)-Omeprazole

The "solid state" alkaline salts of claims 1-2, 4 and 6-7 are nowhere mentioned or defined in the '504 patent specification, and were not present in either the '512 application as filed or the

original claims as presented. Section III-B-1, *supra*; SOF ¶¶ 13-14, 27-31. Rather, in the '512 application as filed, AstraZeneca described preparations of the enantiomers of omeprazole that included those that might be crystalline to an unknown extent (Examples 6 and 7), as well as materials that are reported to be an "amorphous powder," "white crystals" and "white powder" (Examples 1-5). SOF ¶¶ 15-18; Genck Decl. ¶¶ 50-52. There is no indication in the '512 application as filed as to whether or which, if any, of these forms is a "solid state" form as claimed. Because the term is not present, not defined and not described in the '504 patent or the '512 application, a person of ordinary skill in the art would not have been able to make a "solid state" alkaline salt of the claims as of the date of filing, and so the asserted claims are invalid for lack of enablement under Section 112, first paragraph. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 937-40 (Fed. Cir. 2010).

As discussed above, during prosecution, AstraZeneca argued that the claimed "solid state" salts distinguished over the cited anticipatory references, including the Kohl reference (SOF ¶¶ 32-34, 37-39; Genck Decl. ¶ 37-44), making it clear that "solid state" was an essential point of novelty. As such, it was incumbent upon AstraZeneca to fully describe and disclose how to make "solid state" alkaline salts, which it did not do. *Auto. Techs.*, 501 F.3d at 1283 ("the novel aspect of an invention must be enabled *in the patent*") (emphasis added). What one of the proper skill in the art knows cannot substitute for disclosure of novel aspects of the invention in the patent itself. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 375 (D.N.J. 2010). Particularly with respect to the newly added features of the claims, "*it is the specification*, not the knowledge of one skilled in the art, *that must supply the novel aspects of an invention* in order to constitute adequate enablement." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (emphasis added).

Here, the patent specification does not disclose to one of ordinary skill in the art how to

make "solid state" alkaline salts as of the filing date, because the term is neither defined nor explained, and there is no indication that the inventors possessed "solid state" alkaline salts at that time. *See* SOF ¶¶ 13-14, 27-31; Genck Decl. ¶ 34-36. Regardless of what was later said by applicants during prosecution, Section 112 is not satisfied where enablement of one or more key features of a claim rests upon the knowledge of one of ordinary skill that is not in the patent application as filed. *See ALZA Corp.*, 603 F.3d at 937-38; *Eli Lilly*, 731 F. Supp. 2d at 375 (in satisfying the enablement requirement, the knowledge of one skilled in the art cannot substitute for disclosure of novel aspects of the invention). Because the specification of the '504 patent fails to teach those skilled in the art how to make the key feature of "solid state" alkaline salts of (-)-omeprazole added and highlighted during prosecution, it fails to satisfy the enablement requirement.

The Federal Circuit's decision in *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) is squarely on point. In that case, the scope of the limitation at issue covered both mechanical and electronic side impact sensors for an automotive airbag system. While the specification taught extensively regarding mechanical sensors, it only provided one short paragraph and one figure relating to electronic sensors. *Id.* at 1282-83. Neither the one-paragraph description nor the figure, which was referred to as a "conceptional view," offered significant detail concerning how the electronic sensor is built or operated. *Id.* Here, there is no disclosure in the '504 patent devoted to explaining a "solid state" alkaline salt, which by definition cannot be enabled as a result. *Id.*

In *Auto. Techs.*, the court next considered the statements of the applicants during prosecution that the electronic side impact sensors were "essential concept[s] of the invention," and concluded that "[g]iven that the novel aspect of the invention is side impact sensors, it is insufficient to merely state that known technologies can be used to create an electronic sensor."

Id. at 1283-84. Analogously, AstraZeneca's statements during prosecution (as set forth above) that "solid state" alkaline salts were allegedly novel, and the fact that this language was found to distinguish over prior art, mandate a complete description of the term in the '504 patent specification. *Id.* (where the specification provided "only a starting point, a direction for further research" on the use of electronic sensors, the grant of summary judgment was proper).

Finally the *Auto. Techs.* court considered statements in the specification side impact sensing was a "new field" in conjunction with patentees' statement that "at the time it filed the application for the *'253 patent*, it did not know of any electronic sensors used to sense side impact crashes" in concluding that – as a result – "it was especially important for the specification to discuss how an electronic sensor would operate to detect side impacts and to provide details of its construction." *Id.* at 1284. Here, applicants' statements in the specification about the "novelty" of the claimed formulations (SOF ¶ 11 (D.I. 86-2)) and their allegation that no prior art example of any isolated or characterized salt of optically pure omeprazole had been prepared (SOF ¶ 10 (D.I. 86-2)), mandated a fully enabling disclosure of "solid state" alkaline salts, which was never provided.

The rationale for granting summary judgment here is even stronger than in *Automotive Technologies. First,* the patent specification in *Automotive Technologies* at least provided a general overview of the nonenabled embodiment. Here, in contrast, the '504 patent specification provides no disclosure of any kind – not a single mention, definition, figure, diagram, experimental procedure, or analytical data regarding how to make any "solid state" alkaline salt of (-)-omeprazole. Of the three examples (2, 5 and 6) directed to a salt of (-)-omeprazole, none mentions a "solid state" salt. Genck Decl. ¶¶ 49-52. At most, these examples teach that the salts are merely "solid", which this Court has already rejected, and which could not have distinguished prior art amorphous solids during prosecution.

Second, as in *Automotive Technologies,* according to AstraZeneca the relevant field of specific salts of omeprazole enantiomers was in early stages at the time of filing. The specification itself argues that the disclosed salt formulations were "novel" and alleges that no prior art example of any isolated or characterized salt of optically pure omeprazole had previously been prepared (SOF ¶¶ 10-11). Applicants argued during prosecution that the "solid state" alkaline salts of the (-)-enantiomer of omeprazole were not disclosed in the prior art, more easily formulated than prior art formulations, unexpectedly different and clinically advantageous over the prior art, and therefore patentably distinct from prior art compounds. SOF ¶¶ 38, 39. Thus, AstraZeneca's own statements make it clear that the field of endeavor here was even more unpredictable than that in *Automotive Technologies.* The Federal Circuit has made clear that "[t]he law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology." *Chiron*, 363 F.3d at 1254.

Despite the unpredictability that existed, the specification fails to provide those skilled in the art with any teaching – much less any specific and useful teaching – as to the manufacture of a "solid state" alkaline salt of (-)-omeprazole. Under *Automotive Technologies,* the asserted claims of the '504 patent are therefore invalid for nonenablement as a matter of law. *See also Monsanto,* 503 F.3d at 1361 (affirming summary judgment of nonenablement based on (1) "those skilled in the art could not transform a monocot plant cell as of the filing date of the patent application" and (2) the claims required transformation in all plant cells); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005) ("If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their

success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that method actually worked."); *Genentech,* 108 F.3d at 1367-68 ("Where, as here, the claimed invention is the application of an unpredictable technology in the early stage of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching.").

a. One Skilled In The Art Could Not Make A "Solid State" Alkaline Salt Of (-)-Omeprazole Without Undue Experimentation

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." *Genentech Inc. v. Novo Nordisk A/S,* 108 F.3d at 1365 (*quoting In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Enablement is not precluded where a "reasonable" amount of routine experimentation is required to practice a claimed invention; however, such experimentation must not be "undue." *Enzo Biochem*, 188 F.3d at 1371; *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). In *Wands*, the Federal Circuit set forth the following factors to be considered when determining if a disclosure requires undue experimentation: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *Wands*, 858 F.2d at 737.

Absent undue experimentation, a person of skill in the art could not have made or used a "solid state" alkaline salt of (-)-omeprazole in 1995 after reading the specification. *See Monsanto,* 503 F.3d at 1360. Consideration of the *Wands* factors demonstrates conclusively that "solid state" salts are not enabled by the '504 patent specification.

(1-2) The breadth of the claims and the nature of the invention. While the parties

dispute the scope of the term "alkaline salt" *per se*,[7] the scope of the asserted claims includes "solid state" alkaline salt species, whose pharmacologic properties are impossible to predict. Genck Decl. ¶¶ 58-59. In *Martek BioSciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), the district court granted JMOL for the defendant, relying on testimony from the defendant's expert that "claim 1 potentially covers very many – perhaps 10,000 – euryhaline organisms, while the patent discloses only one such organism in a working example." *Id.* at 1379. The Federal Circuit found that other, much narrower claims of the patent-in-suit – encompassing as few as 22 organisms, were enabled, and reversed the district court as to those claims. *Id.* The Federal Circuit did not, however, disturb the district court's finding that Claim 1 was not enabled. Here, the claims at issue are more troubling than Claim 1 in *Martek* – because "solid state" is undefined and the working examples provide no guidance.

Moreover, the nature of the presently claimed pharmaceutical salts – as chemical compounds – is inherently unpredictable. *See, e.g., In re Kubin,* 561 F.3d 1351, 1360 (Fed. Cir. 2009) (referring to biotechnology as "unpredictable art"); *Eisai Co. Ltd. v. Dr.. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (the "chemical arts" are often "unpredictable"). The breadth of the asserted claims and the nature of the invention strongly support a finding of nonenablement.

(3) The quality of experimentation necessary. As discussed above, the specification provides no guidance as to how to prepare "solid state" alkaline salts of (-) omeprazole. For example, it is unclear whether any of the examples disclose a "solid state" alkaline salt as of the filing date, especially given the categorical exclusions AstraZeneca has urged in prosecution (something other than an amorphous solid) and as adopted by the Court in *AZ v.*

[7] Hanmi asserts a narrower scope (six disclosed salts) and AstraZeneca a broader scope (any basic salt), and while the issue will be presented on the *Markman* track, its resolution is not necessary for the present motion to be decided.

DRL (something other than solid form). It is unclear which patent procedure should be used to make any species of "solid state" alkaline salts that are not exemplified in the patent – *i.e.*, starting with the (-)-omeprazole free base, or starting with a sodium or potassium salt of (-)-omeprazole. It is unclear whether "solid state" forms of (-)-omeprazole can exist for certain alkaline salts, given the unpredictability of preparing polymorphs, pseudomorphs, crystalline salts, etc., and determining their suitability or for oral administration as claimed, especially given the large differences in physiochemical properties between different pharmaceutical salts, even those which are "alkaline." Genck Decl. ¶ 57-65. In order to determine how to produce a "solid state" alkaline salt of (-)-omeprazole, a person of ordinary skill in the art would first have to determine what is meant by "solid state" alkaline salts – an impossible task. In short, there can be no dispute that the amount of experimentation needed to develop "solid state" alkaline salts of (-)omeprazole at the time of the effective filing date in 1995 would have been impossible to quantify. Because the specification fails even to address the steps necessary to *identify* a "solid state" alkaline salt of omeprazole, the asserted claims (all of which cover the use of such a salt) are not enabled as a matter of law.

(4-5) The presence or absence of working examples and the amount of direction or guidance presented. As discussed above, the '504 specification is silent as to whether any of the working examples describe how to make and use a "solid state" alkaline salt of (-)-omeprazole. That is because the concept of "solid state" is nowhere presented in the specification. Section III-B-1, *supra*. The lack of any direction or guidance for making a "solid state" salt, and the unpredictable pharmacologic properties of such salts, also supports a finding of nonenablement.

(6-8) The state of the prior art, the relative skill of those in the art, and the predictability or unpredictability of the art. As discussed above, particular solid forms and

properties thereof were unpredictable as of the time of filing (Genck Decl. ¶¶ 58-59); thus there was no meaningful guidance in the prior art that could supply the missing disclosure in the specification with regard to how to make "solid state" alkaline salts of (-)-omeprazole. These factors therefore also support a finding of nonenablement. The inherent unpredictability of the art at the time of filing, considered as a whole with the other *Wands* factors, confirms that the '504 patent disclosure does not permit the claimed subject matter to be made without undue experimentation.

Because the '504 patent as issued and because the '512 application as originally filed are devoid of any mention, much less any enabling disclosure of "solid state" alkaline salts of (-)-omeprazole, claims 1-2, 4 and 6-7 are invalid under Section 112 for lack of enablement as a matter of law.

D. Claims 1-2, 4 And 6-7 Are Invalid Under 35 U.S.C. § 112, Second Paragraph, As Indefinite

A patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. The definiteness requirement of § 112, ¶ 2 "focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the [scope of the] patentee's right to exclude." *Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1338 (Fed. Cir. 2003) (quoting *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1371-72 (Fed. Cir. 2001)). Thus, the definiteness inquiry turns on whether "the claims at issue [are] sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *See Morton. Intl, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). Here, they do not.

When claims 35-41 were added in the February 12, 1997 Amendment in the '512 application (now corresponding to claims 1-7 in the '504 patent), they included the term "solid state" in characterizing the alkaline salt compounds. However, this language appears nowhere in

the '512 application as filed on January 23, 1995 – not in the specification, the original claims or the abstract. Section III-B-1, *supra;* SOF ¶¶ 13-14, 27-31. Clearly, no aspect of the original disclosure describes, defines, discusses or refers to a "solid state" alkaline salt of the (-)-enantiomer of omeprazole. This failure carried forward to issuance, as the specification does not provide any specific teaching, much less a definition of a "solid state" alkaline salt of (-)-omeprazole.

Furthermore, the knowledge of those skilled in the art does not adequately define a "solid state" alkaline salt of (-)-omeprazole. There is no generally accepted understanding of the precise scope of the term "solid state" alkaline salt in the chemical and pharmaceutical fields, particularly in the context of the '504 patent, and the '504 patent provides no guidance. Genck Decl. ¶¶ 45-48. The scope of potential "solid state" alkaline salts is indeterminate, so one of ordinary skill would not know whether a compound is a "solid state" alkaline salt of (-)-omeprazole or not, and thus could not determine whether a given product was included within the scope of the claims. Genck Decl. ¶ 48. This is the hallmark of indefinite claims.

For instance, the Examples of the '504 patent refer to the products therein as "amorphous powders," "white powders," and "crystals," but no characterizing data is provided. Genck Decl. ¶ 50-52. Presumptively, the claims would cover the examples. But as stated above, AstraZeneca argued during prosecution that the claimed "solid state" alkaline salts of omeprazole's enantiomers were different than the amorphous solid reported in the Kohl reference. SOF ¶¶ 32-34; 37-39; Genck Decl. ¶¶ 37-44. Based on the intrinsic record, it is impossible to determine whether "solid state" encompasses amorphous solids in the context of the '504 patent or not, and impossible to know whether an amorphous solid alkaline salt would infringe the patent or not.

Recognizing the fatal ambiguity in the scope of a "solid state" alkaline salt, AstraZeneca had proposed to cabin the term by proposing to the Court in *AZ v. DRL* the construction "a solid form rather than liquid, such as, syrup or oil." That the Court rejected AstraZeneca's proposed construction, finding that "AstraZeneca provided no justification for its proposed construction," supports the ambiguity of the added "solid state" limitation. 2010 U.S. Dist. Lexis 48844 at *26-27.

Even if the Court had accepted the proposed construction, such a construction would have been at odds with the prosecution history as discussed above, because limiting "solid state" to "solid form rather than liquid, such as, syrup or oil" would not distinguish over the "amorphous solids" as disclosed in the prior art. Excluding amorphous solids, one skilled in the art would not be guided by the '504 patent as to whether a "solid state" alkaline salt may be partially crystalline, completely crystalline in a single phase, a mixture of crystalline forms, etc. [8] There is nothing in the '504 patent that discloses any synthesis, assay or test that would allow one skilled in the art to determine whether a potential "solid state" alkaline salt could be prepared and how to do so.

The Federal Circuit has held claims indefinite where a claim contains a term that is "completely dependent on a person's subjective opinion," *Datamize, LLC v. Plumtree Software*, 417 F.3d 1342, 1350 (Fed. Cir. 2005), and that a claim could be indefinite if a term does not have proper antecedent basis where such basis is not otherwise present by implication or the meaning is not reasonably ascertainable. *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) ("The common thread in all of these cases is that claims were held indefinite only where a person of ordinary skill in the art could not determine the bounds of the claims, i.e., the claims were insolubly ambiguous.").

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[8] Claim 4 of the '504 patent compounds the confused intrinsic record by characterizing the solid state salt as in "substantially crystalline form." SOF ¶ 12.

Here, the term "solid state" alkaline salt is a moving target. Can solid state alkaline salts be amorphous *or not*? Can they be partially crystalline *or not*? There is no reasonable way for a potential competitor or the public to determine which compounds may constitute a "solid state" alkaline salt of (-)-omeprazole. As explained in *Halliburton,* the crucial purpose of a definiteness inquiry is to give the public notice as to how to meet – and to avoid meeting – patent claims. *See also United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942) ("The statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."). The '504 patent fails to inform the public how to determine whether a chemical entity is or is not a "solid state" alkaline salt of (-)-omeprazole. The claims are therefore indefinite and should be held invalid under 35 U.S.C. § 112.

III. CONCLUSION

For the reasons stated above, Hanmi respectfully request that the Court grant its Motion for Summary Judgment that the asserted claims of the '504 patent are invalid under 35 U.S.C. § 112, first and second paragraphs.

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2011, I caused a copy of the foregoing DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT NO. 3: INVALIDITY OF U.S. PATENT NO. 5,714,504 - CLAIMS 1-2, 4, 6 AND 7 BASED ON "SOLID STATE" to be served upon the following counsel through the Court's ECF system and via mail:

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